CHARGE: 502(f)(1)—when shipped, the labeling (syringe) failed to bear adequate directions for use of the article as a means of self-administration of insulin; and 502(j)—the article was dangerous to health when used according to the dosage scales inscribed on its label.

DISPOSITION: 6-19-61. Default—destruction.

## DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

6662. Penicillin G potassium tablets. (F.D.C. No. 45896. S. Nos. 83-301/23 R.)

QUANTITY: 578 100-tablet btls. of 50,000 unit penicillin G potassium tablets and various drums, cartons and bottles of 50,000, 100,000, 200,000, 250,000, 400,000, and 500,000 unit tablets of penicillin G potassium, totaling 3,369,913 tablets in all, at New York, N.Y., in possession of Pure Laboratories, Inc.

SHIPPED: During 1960 and 1961, from various manufacturers in the State of New York.

RESULTS OF INVESTIGATION: The tablets were repacked by the dealer from penicitlin G potassium tablets received from various manufacturers who manufactured the tablets from penicillin powder received in interstate commerce.

LIBELED: 5-22-61, S. Dist. N.Y.

CHARGE: 502(1)—while held for sale, the article purported to be a drug composed wholly or in part of penicillin and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 6-27-61. Consent—claimed by Pure Laboratories, Inc., and released to be brought into compliance with the law.

## DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

6663. Amphetamine sulfate tablets and dextro-amphetamine sulfate tablets. (F.D.C. No. 46116. S. Nos. 31–132/6 R.)

QUANTITY: 2 50,000-tablet drums, 1 btl. of 1,498 tablets, 1 btl. of 2,497 tablets, and 1 can of 6,445 tablets of amphetamine sulfate; 1 btl. of 365 tablets of dextro-amphetamine sulfate, at Mobile, Ala.

SHIPPED: Prior to 7-10-61, from Woodside, Long Island, N.Y., and thereafter transported from Moss Point, Miss., to Mobile, Ala., by Jonathan Mead.

LIBELED: 7-17-61, S. Dist. Ala.

CHARGE: 502(f)(1)—while held for sale by Jonathan Mead, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were prescription drugs which were not and would not be lawfully used nor lawfully dispensed by a practitioner licensed by law to administer such drugs in the course of his professional practice.

DISPOSITION: 8-16-61. Default—destruction.

6664. Sea brine. (F.D.C. No. 45845. S. No. 54-441 R.)

QUANTITY: 8 cases of 24 8-oz. btls. each at Minneapolis, Minn.

SHIPPED: 1-18-61, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc.

<sup>\*</sup>See also No. 6661.